

REMARKS

Applicants respectfully submit that, contrary to the examiner's assertion, claim 1 of the application does provide a technical feature over the cited prior art, as explained below, and that, therefore, all of the now pending claims should be examined together.

Applicants herein have amended the claims of the application such that they now are directed to method of preparing a nucleic acid-cationic immunoliposome complex, a complex prepared by that specific method, a method of providing a therapeutic molecule to an animal in need thereof by administering a complex prepared by the specified method, and a kit for preparing complexes in accordance with the specified method. All of the pending claims thus are linked by the steps of the method of preparation of the nucleic acid-cationic immunoliposome complex, and that method is not taught or suggested by the Compagnon et al. reference.

The ratio of components (antibody or antibody fragment to liposome and nucleic acid to liposome) set forth in each of the independent claims is a key factor in the formation of a complex that is effective *in vivo* for delivery of DNA for gene therapy. The ratios of the components in the complexes made by Compagnon et al. are quite different from those set forth in the present claims, and result in complexes that are distinguishable from those of the present invention. For example, Compagnon et al. state in their paper that when they added DNA to their antibody -liposomes "noticeable aggregation occurred" (see the paragraph bridging pages 130 -131). This aggregation would preclude the use of any complex formed this way from being useful *in vivo* (and

indeed, no *in vivo* testing is reported by Compagnon et al.) as introduction of a precipitate into the blood stream would have life-threatening consequences for the patient. The method of preparation developed by the present inventors does not result in the formation of a precipitate and the resultant complexes are not toxic upon administration to animals. See Example 12 of the present application.

Inasmuch as claim 1 (and the other independent claims) does provide a technical feature that is distinguished over the prior art, Applicants respectfully submit that the pending claims do provide unity of invention. Applicants therefore request that all of the pending claims, as amended, be examined together.

Applicants recognize, however, that in order to be fully responsive to the outstanding Action they must elect one of the groups of claims listed by the examiner. In the event that the examiner makes the restriction requirement final, Applicants hereby elect the claims of Group II, claims 1-12, for examination on the merits.

<input checked="" type="checkbox"/> Customer Number or Bar Code Label 6449					
Name	Barbara G. Ernst, Reg. No. 30,377				
Signature	Barbara G. Ernst			Date	April 30, 2004
Address	Rothwell, Figg, Ernst & Manbeck Suite 800, 1425 K Street, N.W.				
City	Washington	State	D.C.	Zip Code	20005
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031